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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6:
A61K 9/27, 31/56

(11) International Publication Number: WO 00/00181

(43) International Publication Date: 6 January 2000 (06.01.00)

(21) International Application Number: PCT/US99/14351

(22) International Filing Date: 24 June 1999 (24.06.99)

(30) Priority Data: 09/105,838 26 June 1998 (26.06.98) US

(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Application

US 09/105,838 (CIP) Filed on 26 June 1998 (26.06.98)

(71) Applicant (for all designated States except US): LDS TECH-NOLOGIES, INC. [US/US]; 305 Chelsea Parkway, Boothwyn, PA 19061 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): SAIDI, Zahir [DZ/US]; 919 Hall Street, Philadelphia, PA 19147 (US). KLYASH-CHITSKY, Boris [RU/US]; 9204 Picasso Court, Newark, DE 19702 (US).

(74) Agents: ELDERKIN, Diane, B. et al.; Woodcock Washburn Kurtz Mackiewicz & Norris LLP, 46th Floor, One Liberty Place, Philadelphia, PA 19103 (US).

(81) Designated States: AU, CA, IL, JP, MX, NO, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published

With international search report.

(54) Title: AQUEOUS COMPOSITIONS CONTAINING CORTICOSTEROIDS FOR NASAL AND PULMONARY DELIVERY

(57) Abstract

The present invention provides compositions containing corticosteroid compounds as active agents for the treatment of ailments and diseases of the respiratory tract, particularly the lungs, by way of nasal and pulmonary administration. The corticosteroid compounds are present in a dissolved state in the compositions. The compositions can be formulated in a concentrated, essentially non-aqueous form for storage or in a diluted, aqueous-based form for ready delivery. In a preferred embodiment, the corticosteroid composition contains an ethoxylated derivative of vitamin E and/or a polyethylene glycol fatty acid ester as the high-HLB surfactant present in the formulation. The compositions are ideally suited for inhaled delivery with a nebulizer or for nasal delivery.

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IPC(6) :A61K 9/27, 31/56									
US CL: 424/450; 514/179, 180 According to International Patent Classification (IPC) or to both national classification and IPC									
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C. DOCUMENTS CONSIDERED TO BE RELEVANT									
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Y	US 5,478,860 A (WHEELER et al.) 2 document.	1-21							
Y	US 4,567,161 A (POSANSKI et al.) 28 January 1986, see entire 1-21 document.								
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Y	LY, J. et al. 'Evaluation and Application of Hydrophilic Tocopherol Polyethylene Glycol Derivatives as Enhancers of Drug Solubility.' In: College of Pharmacy and Allied Health Professions, St. John's University, Jamaica, NY, Presentation ID: 3419, 05 November 1997, 1 page summary.								
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